UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: August 9, 2020

SUBJECT: Efficacy Review for Oxivir TB,
EPA Reg. No. 70627-56
DP Barcode: 458174
E-submission No. 51036

FROM: Kristen Willis, Chief
Product Science Branch
Antimicrobials Division (7510P)

TO: Joe Varco, PM 33/Menyon Adams
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Diversey

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen peroxide	0.5%
Other Ingredients	99.50%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Spray

Submission type: Label Amendment

Currently registered efficacy claim(s): Hard surface disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal), non-food contact sanitizer for hard surfaces and spot sanitizer for soft surfaces

Requested action(s): Add electrostatic spray directions for use

Documents considered in this review:

- Cover letter from applicant to EPA dated 5/29/2020
- Proposed label dated 5/31/2020
- Data Matrix (EPA Form 8570-35) dated 5/29/2020
- 2 efficacy studies (MRIDs 51177600 and 51177601)
- Confidential Statement of Formula (EPA Form 8670-4) dated 1/5/2012

II PROPOSED DIRECTIONS FOR USE

For Use as a Cleaner or One-Step Disinfectant Product with an Electrostatic Sprayer:
1. Pre-clean heavily soiled areas.
2. Before spraying, make sure the room is unoccupied and the operator is wearing adequate PPE as described on the product Safety Data Sheet. Using the sprayer, apply disinfectant evenly over the hard, non-porous inanimate surface to be cleaned, 2-3 feet from surface, making sure to wet surfaces thoroughly.
3. All surfaces must remain wet for 1 minute. Use a 5-minute contact time for Tb and a 3 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Allow the treated room to remain unoccupied for 15 minutes before reentering.

III STUDY SUMMARY

1.	**MRID**	51177601	
Study Objective		AOAC Germicidal Spray Test via Electrostatic Sprayer	
Testing Lab; Lab Study ID		Diversey Micro Lab	
Experimental Start Date		04/15/2020	**Study Completion Date:** 04/20/2020
Test organism(s) ☐ **1** ☒ **2** ☐ **3** ☐ **4+**		Pseudomonas aeruginosa ATCC #15442 and Staphylococcus aureus ATCC #6538	
Test Method		AOAC Germicidal Spray Test 961.02(EPA MB-06-09)	
Application Method		Electrostatic spray; The electrostatic sprayer was sprayed onto the glass carriers from a distance of 3 feet at a 45-degree angle until thoroughly wet.	
Test Substance Preparation	**Name/ID**	Oxivir TB	
	Lots ☒ **1** ☐ **2** ☐ **3**	Lot # 10302019NW01	
	Preparation	Tested concentration: greater than Nominal, production lot	

		Tested Dilution: Ready to use Diluent: N/A
Soil load		5% fetal bovine serum in viral inoculum
Carrier type, # per lot		Glass carriers, 10 per organism
Test conditions		Contact time: 55 seconds Temperature: Ambient Relative humidity: 40+/- 5%
Neutralizer		2X Letheen + 1% Sodium Thiosulfate (primary neutralizer) 2X Letheen for the secondary neutralizer.
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		The study was not conducted under GLP. The electrostatic sprayer used in the testing was the E-mist 360 which discharges particles greater than 40 microns from its nozzle.

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	No. of carriers exhibiting growth/Total No. tested	Average Log_{10} CFU/carrier
55 seconds, RTU, electrostatic spray, 5% fetal bovine serum, Lot 10302019NW01			
51177601	Pseudomonas aeruginosa ATCC #15442	0/10	$>1x10^5$
	Staphylococcus aureus ATCC #6538	0/10	$>1x10^5$

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51177601	Disinfectant	Hard non-porous surface	Electrostatic spray	55 seconds	5% fetal bovine serum	N/A	• *Pseudomonas aeruginosa* ATCC #15442 • *Staphylococcus aureus ATCC #6538*	**Yes***

* A full set of confirmatory data should be submitted within 1-year consistent with the instructions in the expedited guidance for adding electrostatic spray (https://www.epa.gov/pesticide-registration/expedited-review-adding-electrostatic-spray-application-directions-use)

VI LABEL COMMENTS

Label Date/Identification Number: 05/29/2020

1. The proposed label claims that the product, Oxivir TB, when applied using an electrostatic sprayer, is an effective disinfectant on hard, non-porous surfaces in the presence of 5% organic soil for a 1-minute contact time:

   Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (Strain USA-WA1/2020, Source: BEI Resources NR-52281)

   This claim is **partially acceptable** as it is partially supported by the submitted data. The data do not support use for contact times greater than 1 minute. The directions for use for electrostatic spray for TB (5 minutes) and fungi (3 minutes) should be removed. In addition, add the following statement to the directions for use "Do not use electrostatic sprayer to treat surfaces against TB and fungi"

2. Within 1-year, a full set of confirmatory data should be submitted to EPA consistent with the instructions in the expedited guidance for adding electrostatic spray (https://www.epa.gov/pesticide-registration/expedited-review-adding-electrostatic-spray-application-directions-use). This should include data for bacteria and the hardest to kill virus at or below the nominal concentration and a wetness test to verify the surface is visibly wet for the duration of the contact time when applied using electrostatic spray.

3. Consistent with the electrostatic spray guidance, the following should be added to the proposed label:

   a. Specify that the spray droplet particle size (regardless of the ability to change nozzles that impact particle size) should be limited to a volume median diameter (VMD) ≥40 µm1
   b. Include the minimum and maximum spray distance from the application equipment to the treated surface that is supported by the efficacy data, and instructions to reapply if the surface dries before the contact time is achieved.
      i. Note: The tested distance, 3-feet, from the surface should be used as the maximum distance. Please also specify a minimum distance.
   c. Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF.
   d. Specify that bystanders and pets must not be in the room during application,
   e. The following personal protective equipment (PPE) should be specified on the product label as part of the electrostatic spray directions for use:
      i. As hydrogen peroxide has a high vapor pressure (greater than 1. X 10-4 mm Hg), specify the use of half face respirators with chemical specific cartridges and N95 filters.
   f. Specify that end-users should consult the user manual for the specific electrostatic sprayer that is being used.

4. Make the following changes to the proposed label:
   a. On page 2,
      - Revise "Disinfectant for use with electrostatic sprayers" to specify not for use to treat surfaces against TB and fungi
      - Revise "Approved for electrostatic sprayers" to "Tested using electrostatic sprayers".